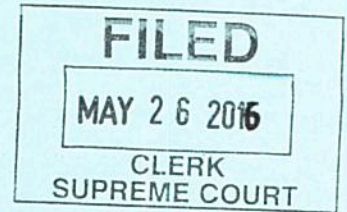


COMMONWEALTH OF KENTUCKY
SUPREME COURT
NO. 2015-SC-000465-D
(2014-CA-001050)



ALEX ARGOTTE, M.D.

APPELLANT


V.

McCracken Circuit Court
2008-CI-01512

JACQULYN G. HARRINGTON

APPELLEE

BRIEF FOR APPELLEE, JACQULYN G. HARRINGTON



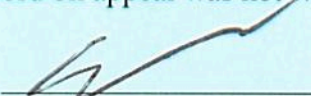
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CERTIFICATE OF SERVICE

I hereby certify that ten (10) originals of the foregoing have been served via U.S. Mail upon: Susan Stokely Clary, Clerk of the Supreme Court of Kentucky, State Capitol, Room 209, 700 Capital Avenue, Frankfort, Kentucky 40601, and that a true and accurate copy of the foregoing has been served upon Samuel Givens, Jr., Clerk of the Kentucky Court of Appeals, 300 Democrat Drive, Frankfort, Kentucky, 40601-9229, Hon. Craig Z. Clymer, Circuit Court Judge, Division II, McCracken Circuit Court, P.O. Box 1455, Paducah KY 42003, and Hon. James Sigler, WHITLOW ROBERTS HOUSTON & STRAUB PLLC, P.O. Box 995, Paducah, Kentucky, 42002-0995, attorney for Appellant, Alex Argotte, M.D., on the 24th day of May 2016. Appellee further certifies that the record on appeal was not withdrawn.



Clifton A. Boswell

I. STATEMENT CONCERNING ORAL ARGUMENT

Appellee does request the opportunity to present oral arguments to this Court, and believes that doing so may be helpful in further clarifying the issues before the Court.

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III. COUNTERSTATEMENT OF THE CASE

A. INTRODUCTION

1. Chronological Summary of Facts

On May 31, 2005, Ms. Harrington Jacquelyn Harrington (hereinafter "Ms. Harrington" and/or "Appellee") underwent a gastric bypass surgery performed by Alex Argotte, M.D. (hereinafter "Dr. Argotte" and/or "Appellant"). (Record, page 557, Deposition of Ms. Harrington, page 35). On May 10, 2005, Dr. Argotte performed a procedure on Ms. Harrington to implant what is known as an Inferior Vena Cava Filter ("IVC filter") for the purpose of preventing a pulmonary embolism. (Record, page 557)

There were no complications with the gastric bypass surgery. However, in December of 2007, Ms. Harrington presented to the Emergency Room at Regional Medical Center/Trover Clinic in Madisonville with severe chest pain. It was determined that the IVC filter implanted in May of 2005 had fractured, and that fragments of the IVC filter had migrated to her lungs. (Record, Deposition of Ms. Harrington, pages 50-51).

On January 7, 2008, surgery was performed to remove the remainder of the filter. (Record, Deposition of Ms. Harrington, page 77). The surgery was successful in removing the main component of the IVC filter; however remaining fragments in her lungs could not be removed. (Record, Deposition of Ms. Harrington, pages 61, 84). The remains of this filter are permanently lodged in her chest, causing her physical and emotional pain, including the fear that these fragments could migrate again and cause her serious harm or even death. (Record, Deposition of Ms. Harrington, pages 19, 56, 78-79, 84).

Ms. Harrington was deposed on October 27, 2009. In that deposition she stated that Dr. Argotte never advised her that there were any risks to having an IVC filter placed. This includes not being advised that the IVC filter could fracture or migrate, or any other risk. (Record, Deposition of Ms. Harrington, pages 28-32, 77. She testified that Dr. Argotte told her that he would not perform the gastric bypass procedure unless she agreed to have the IVC filter placed. (Record, Deposition of Ms. Harrington pages 26-27). She testified that the only risk he ever advised her of was the risk that she could develop a blood clot *if she did not* have an IVC filter placed. (Record, Deposition of Ms. Harrington page 28).

She was questioned about a consent form that she signed, which was Exhibit 5 to the deposition transcript. She testified that neither Dr. Argotte or his staff explained that form to her. She was handed a "bunch" of papers, one of which was this consent form, and felt that she was being rushed by Dr. Argotte's assistant to sign them all, with no explanation given. (Record, Deposition of Ms. Harrington pages 39-40). This consent form which was attached to the deposition contains a signature line for Dr. Argotte, but does not contain his signature. (Record, Deposition of Ms. Harrington, Exhibit 5).

2. Procedural History

Suit was filed on December 22, 2008. The initial Complaint included a product liability claim against the manufacturer of the IVC filter, along with a claim that Dr. Argotte breached the standard of care required of a reasonably competent physician relating to the implantation of the IVC filter. (Record, pages 1-4). The product liability claim was resolved and dismissed with prejudice. (Record, pages 445-447). The

Complaint was amended June 24, 2011 to include an allegation of lack of informed consent against Dr. Argotte. (Record, pages 507-509).

Through the course of litigation, a decision was made by Ms. Harrington and her counsel to only pursue the claim of lack of informed consent and not to pursue a claim of medical negligence against Dr. Argotte relating to the implantation of the IVC filter. Thus the only issue that would be tried was the claim of lack of informed consent as it related to the IVC filter. Those claims include the failure of Dr. Argotte to inform her that the IVC filter was retrievable filter (as opposed to permanent IVC filters, which also were utilized at the time), and that it carried the risk of fracture and migration.

The trial had previously been continued multiple times. (Record, pages 502-506, 512-516, 521-522). By Order dated February 14, 2013, this matter was set for a Pretrial Conference on February 28, 2014 and jury trial on March 17, 2014. (Record, pages 523-527).

In compliance with pretrial orders of the court, Ms. Harrington submitted her List of Witnesses on February 21, 2014 as part of her Trial Brief (Record, pages 556-561) and again on February 25, 2014 as part of her Amended Trial Brief (Record, pages 562-567).

Previously in this action, Ms. Harrington had disclosed as an expert Ralph Silverman, M.D., who was deposed by Dr. Argotte. (Record, Deposition of Ralph Silverman, M.D.). After deciding to only pursue the claim of lack of informed consent Ms. Harrington decided not to present the testimony of Dr. Silverman or any medical expert at trial. Counsel for Ms. Harrington had concluded that under the facts of this case, and pursuant to the Kentucky Supreme Court decision in Keel v. St. Elizabeth Med. Ctr., 842 S.W.2d 860 (Ky. 1992), expert testimony was not required. Ms. Harrington's

List of Witnesses, referenced above and served both on February 21, 2014 and (as amended) on February 28, 2014, did not include Dr. Silverman or any expert witness.

At the Pretrial Conference on February 28, 2014, defense counsel was previously on notice from Ms. Harrington's List of Witnesses that Ms. Harrington would not be presenting an expert witness at trial. Though he could have done so, Dr. Argotte did not file a motion for summary judgment attempting to argue that lack of an expert witness was fatal to Ms. Harrington's case.

On the morning of trial, March 17, 2014, counsel for Ms. Harrington presented his opening statement to the jury. In that opening statement, counsel for Ms. Harrington told the jury (as Dr. Argotte's counsel and the trial court had known for over three weeks) that Ms. Harrington would not be presenting an expert witness to tell the jury that Dr. Argotte failed to obtain informed consent. Ms. Harrington's counsel provided a preview of the anticipated evidence that would demonstrate an obvious lack of informed consent. Members of the jury were told that they could use their own common sense and life experiences to determine whether there was lack of informed consent. (Record, Opening Statement of Plaintiff, CD/DVD of trial, March 17, 2014).

Immediately following Ms. Harrington's opening statement, counsel for Dr. Argotte moved for directed verdict. He argued that an expert witness was absolutely required for Ms. Harrington to pursue its claim of lack of informed consent. Lack of an expert witness, according to Dr. Argotte, was absolutely fatal to Ms. Harrington's case. (Record, Hearing on Motion for Directed Verdict, CD/DVD of trial, March 17, 2014).

Ms. Harrington vehemently objected to Dr. Argotte's motion heard on a procedural basis--that it was inappropriate for this motion to be heard the morning of

trial. Ms. Harrington also objected to this motion substantively, arguing that Kentucky law does not always require presentation of an expert witness in a case of lack of informed consent. Ms. Harrington furthermore argued that it was procedurally incorrect to rule on a motion for directed verdict prior to presentation of evidence. (Record, Hearing on Motion for Directed Verdict CD/DVD of trial, March 17, 2014).

Over the objections of Ms. Harrington, the trial court sustained Dr. Argotte's motion for directed verdict. The trial court's ruling on this matter ended the trial prior to the presentation of any evidence. (Record, Hearing on Motion for Directed Verdict CD/DVD of trial, March 17, 2014). An "Order Granting Directed Verdict in Favor of Defendant Alex Argotte, M.D." was entered on March 21, 2014 (Record, pages 581-584) and received by Ms. Harrington a few days later. Ms. Harrington immediately filed a "Motion to Alter, Amend and Vacate Judgment and Motion for Continuance of Trial." (Record, pages 585-593). This motion tolled the time period for filing of a notice of appeal pursuant to CR 73.02(e).

In this motion, Ms. Harrington argued that the trial court's "directed verdict" should be set aside because its entry was improper from both a procedural and substantive standpoint. Ms. Harrington argued that this was actually a motion for summary judgment that entitled Ms. Harrington to ten (10) days notice. Ms. Harrington reiterated that under Kentucky law, an expert witness was not required in this case, and that Ms. Harrington's proof would have demonstrated that. It was erroneous, therefore, for the trial court to enter judgment prior to Ms. Harrington presenting her proof. Finally, Ms. Harrington argued that if the trial court remained steadfast that Ms. Harrington's case required an expert, that the trial court should grant Ms. Harrington a continuance so that

she can present an expert. (Record, pages 585-593). A hearing was held on May 23, 2014, and Ms. Harrington's motion was denied. (Record, pages 613-617).

A Notice of Appeal was subsequently filed. (Record, pages 618-620). The matter was fully briefed and argued orally before the Kentucky Court of Appeals. The Kentucky Court of Appeals reversed the judgment of the McCracken Circuit Court, unanimously holding that directed verdict should not have been entered prior to the introduction of evidence. Dr. Argotte petitioned this Court for Discretionary Review, which was granted.

IV. ARGUMENT

A. DIRECTED VERDICT SHOULD NOT HAVE BEEN ENTERED PRIOR TO INTRODUCTION OF EVIDENCE

Ms. Harrington argued before the Kentucky Court of Appeals that this motion brought by Dr. Argotte on the morning of trial should not have been considered to begin with--at least not on the morning of trial without notice to Ms. Harrington. Ms. Harrington argued that, because the motion was being presented prior to the introduction of evidence, it should have been treated as a motion for summary judgment, with ten days notice being provided to Ms. Harrington pursuant to CR 56. The Kentucky Court of Appeals, in reversing the trial court, contained its analysis to whether entry of directed verdict was appropriate, when no evidence had been introduced.

The Kentucky Court of Appeals recognized, citing to well-established law, that under CR 50.01, a directed verdict requires the trial court to draw all inferences from the evidence in favor of the non-moving party, citing Lee v. Tucker, 365 S.W.2d 849 (Ky. 1963) and CR 50.01. The Kentucky Court of Appeals noted that the high standard for appellate review of a directed verdict requires the appellate court to "ascribe to the

evidence all reasonable inferences and deductions which support the claim of the prevailing party." Bierman v. Klapheke, 967 S.W.2d 16 (Ky. 1998). The Kentucky Court of Appeals pointed out that the language of CR 50.01 and Kentucky case law contemplates the introduction of "some evidence" before granting a directed verdict.

The Kentucky Court of Appeals then pointed out that an opening statement does not constitute "evidence", citing Wheeler v. Commonwealth, 121 S.W.3d 173 (Ky. 2003) and other law. Therefore, nothing stated in Ms. Harrington's opening statement should be considered for the purpose of evaluating the evidence according to the proper standard for directed verdict.

The Kentucky Court of Appeals recognized the fact that under Kentucky law, directed verdict may be entered following a plaintiff's opening statement only under very rare and limited circumstances. That limited exception is if counsel makes an admission that is absolutely fatal to the cause of action. The Court of Appeals citing Riley v. Hornbuckle, 366 S.W.2d 304 (Ky. 1963) and other law.

B. MS. HARRINGTON DID NOT MAKE A "FATAL ADMISSION" IN OPENING STATEMENT

The "admission" made by counsel during opening statements was that no medical expert would be presented in support of Ms. Harrington's claim for lack of informed consent. Under Kentucky law, however, as held by this Court in Keel v. St. Elizabeth Med. Ctr., 842 S.W.2d 860, 862 (Ky. 1992), a claim for lack of informed consent may proceed without expert testimony, "if the failure to disclose is so obvious that a layperson can recognize the necessity of such disclosure to a patient." The Kentucky Court of Appeals recognized that whether or not said failure to disclose falls into this category depends upon the evidence that is presented.

The Kentucky Court of Appeals properly recognized that the trial court prematurely determined that an expert witness was absolutely required without permitting Ms. Harrington to present evidence to the jury which may have demonstrated that the failure to disclose was obvious and apparent to a layperson.

C. ENTRY OF DIRECTED VERDICT PRIOR TO PRESENTATION OF EVIDENCE IS HIGHLY DISCOURAGED UNDER KENTUCKY LAW

Entry of directed verdict prior to the conclusion of a plaintiff's proof is highly discouraged under Kentucky law and reserved only for extreme circumstances which did not exist in this case.

In the hearing of this motion for directed verdict Dr. Argotte argued that Kentucky law recognizes entry of directed verdict prior to any evidence being presented, and cited Lambert v. Franklin Real Estate Co., 37 S.W.3d 770 (Ky. App. 2000). The *Lambert* case actually discourages entry of directed verdict prior to evidence being presented, although it does not absolutely prohibit it.

Lambert was a wrongful death case in which two men were electrocuted, and one or more utility companies were alleged to be liable. Directed verdict was not entered in *Lambert* following opening statements, as occurred in the case that is before this Court. In *Lambert*, directed verdict was entered *after a significant amount of evidence was presented* by the plaintiff, including testimony of plaintiff's expert. The plaintiff provided testimony that was fatal to plaintiff's case in that it established that the utility companies had no duty of care to the injured party. The Court of Appeals stated as follows:

In general, a directed verdict should not be granted until the conclusion of the plaintiff's case. Rule 50.01 recognizes the right of a party to move for a directed verdict *at the close* of the

evidence offered by the opposing party' [citation omitted]. Nevertheless, Kentucky cases recognize the power of a trial court to decide a case upon the opening statement of counsel where they clearly and definitely disclose no cause of action or no defense, or admit facts the existence of which precludes a recovery by their clients. However, the cases admonish that such a practice is a dangerous one and the power should be exercised with caution. [citations omitted]. (Emphasis Added). *Id.* at 774.

Clearly, the practice of entering directed verdict prior to the presentation of any proof by a plaintiff is highly discouraged under Kentucky law as noted by the Kentucky Court of Appeals in *Lambert*. This is because, as further noted by the court in *Lambert*:

A directed verdict is appropriate when, 'drawing all inferences in favor of the non-moving party, a reasonable jury could only conclude that the moving party was entitled to a verdict.' The trial court is required to 'consider the evidence in its strongest light in favor of the party against whom the motion is made and must give him the advantage of every fair and reasonable intendment that the evidence can justify. *Id.* at 775.

In *Lambert*, plaintiff's witnesses made admissions that basically established as a matter of law that the defendant had no duty of care. In the case at bar, it cannot be said that after Ms. Harrington's opening statement, Ms. Harrington "clearly and definitely disclose[d] no cause of action or no defense, or admit[ted] facts the existence of which preclude[d] a recovery by their clients".

D. TRIAL COURT IMPROPERLY CONSTRUED *KEEL*

The trial court's entry of directed verdict was predicated upon an erroneously narrow construction of *Keel v. St. Elizabeth Med. Ctr.*, 842 S.W.2d 860, 862 (Ky. 1992). The Kentucky Supreme Court decision in *Keel* establishes that an expert witness is not required in cases in which lack of informed consent can be determined by a layperson using common sense. Ms. Harrington planned to present evidence demonstrating that her case fell into the circumstances in which an expert was not required, but was denied that

opportunity to do so. Under the directed verdict standard, the Court was required to draw all inferences in favor of Ms. Harrington when viewing the evidence, but failed to do so, committing reversible error.

Dr. Argotte urges adoption of the trial court's narrow interpretation of *Keel*, which was rejected by the Kentucky Court of Appeals. The trial court erroneously interpreted *Keel* to require an expert witness in all lack of informed consent cases, unless the evidence would be that the patient received *absolutely no* information about a procedure. This is simply not the holding of *Keel*. The holding of *Keel* is a general principle of law, which is that an expert witness is not required in a lack of informed case when the lack of informed consent is obvious even to a layperson. *Keel, supra* at 862.

In *Keel*, the patient had a negative reaction to a CT scan that included an injection of contrast dye. The hospital and ordering physician provided no information to the patient about any risks of the procedure. The hospital did ask the patient questions about whether he had ever had previous adverse reactions to contrast materials, which would have implied to the plaintiff that there was a risk of an adverse reaction. Under the circumstances of that case, the Kentucky Supreme Court concluded that no expert was required. *Keel, supra*.

The trial court construed the holding of *Keel* to apply only to the facts that occurred in *Keel* in which the patient was not told about any risks of a procedure. The trial court found it significant that Ms. Harrington signed a consent form, although, as the Kentucky Court of Appeals has noted, this consent form was never admitted into evidence, and is not part of the court record. The trial court erroneously extrapolated from the *Keel* decision that if a patient receives *any information at all* about the risks of a

procedure, which could include being provided a consent form which is signed--the requirement for an expert witness is automatically and absolutely triggered.

Nowhere in the *Keel* decision does the Kentucky Supreme Court limit its holding to situations in which the patient received absolutely no information about the risks of a procedure. In *Keel*, the Kentucky Supreme Court does not set forth any specific factors for determining whether "the failure [to adequately inform a patient] is so apparent that laymen may easily recognize it, or infer it from evidence within the realm of common sense." *Keel, supra* at 862.

Dr. Argotte cites no caselaw for the proposition that the existence of a limited signed consent form triggers the requirement for an expert witness in a lack of informed consent case. Even if Dr. Argotte's argument were to be accepted, the trial court erred by factoring into its analysis a consent form which had never been introduced into evidence. Had Ms. Harrington's evidence been presented, that evidence would have been that the consent form did not fully set forth the risks that ultimately became reality, and that the contents of that consent form were never explained to Ms. Harrington in any way. The evidence would also have shown that Dr. Argotte did not verbally, or through a consent form or any documentation, explain to Ms. Harrington that the IVC filter was designed to be temporary or retrievable.

E. ENTRY OF DIRECTED WAS INAPPROPRIATE EVEN UNDER TRIAL COURT'S NARROW INTERPRETATION OF *KEEL*

As indicated above, Ms. Harrington's lack of informed consent claim has two main components. The first is that Dr. Argotte failed to inform her of any risks of the IVC filter, including the risk of fracture and migration. The second has to do with the fact that Dr. Argotte placed a retrievable IVC filter, versus a permanent IVC filter. Dr.

Argotte did not discuss with her the options of having a retrievable versus permanent filter, or of the risks/benefit analysis of leaving the filter in, versus retrieving it. The consequence of this was that Ms. Harrington did not opt to have the filter removed, due to her ignorance regarding the filter's retrievability. Two years later, the filter fractured and migrated. Ms. Harrington would have presented evidence that Dr. Argotte did not hold hospital staff privileges to perform an IVC filter removal (which he also failed to disclose to her) which likely explains why he did not tell her that the filter could be retrieved.

The evidence would have been undisputed that Ms. Harrington did not sign a consent form for the placement of a *retrievable* IVC filter, and was not provided any documentation setting forth the risks specific to a retrievable IVC filter, or explaining that she could opt to have the filter removed after recovering from her gastric bypass surgery. Ms. Harrington would certainly have testified that she was never told that the filter was made to be retrievable, and that she was never advised of any risk/benefit analysis to having a retrievable filter versus a permanent one. Therefore, as to the issues surrounding retrievability of the IVC filter, Ms. Harrington received absolutely no information. Even under the trial court's faulty interpretation of *Keel*, an expert would not have been required on this issue, since the patient was given no information.

F. EXPERT WITNESS WOULD NOT HAVE AIDED THE JURY IN DETERMINING WITNESS CREDIBILITY

Even if this Court were to conclude that, as a matter of law, Ms. Harrington could not have presented evidence demonstrating an obvious lack of informed consent that could be recognized by a layperson, an expert likely would not have aided the jury in rendering a verdict. That is because the dispute was likely to come down--not to *whether*

Dr. Argotte should have informed Ms. Harrington as to certain risks/options, but whether he actually did.

Ms. Harrington would have testified in a manner consistent with her deposition testimony that Dr. Argotte never advised her that there were any risks at all to having an IVC filter placed. She would have testified that he never advised her that there was any risk that the IVC filter could fracture or migrate, potentially causing even death. She would have testified that she was handed this consent form with a host of other papers and simply told to sign them if she wanted to have the gastric bypass surgery, with no explanation as to any risks or what the consent form meant. (Record, Deposition of Ms. Harrington, pages 27, 28, 32, 39, 40). Her mother, Sharon Carter was also expected to testify. Ms. Carter was present when the consent form, along with several other documents were presented to Ms. Harrington for her signature without any explanation. (Record, Deposition of Ms. Harrington, page 43).

Dr. Argotte would also have been called as a witness by Ms. Harrington. It was anticipated that he would have agreed that Ms. Harrington should have been told about the risks of fracture and migration of the IVC filter. He has never denied this, and did not deny it in his deposition testimony. In his deposition testimony, he agreed that both fracture and migration of an IVC filter were a risk. (Record, Deposition of Dr. Argotte, page 43). It is anticipated, however, that Dr. Argotte would testify in direct contradiction to Ms. Harrington's testimony, and state that he did verbally tell Ms. Harrington of the risks of fracture and migration of the IVC filter.

Dr. Argotte may have agreed that Ms. Harrington was entitled to be advised that the filter was retrievable. Whether Dr. Argotte would have asserted that he fully

explained to Ms. Harrington the fact that this IVC filter was retrievable, or agreed that he did not tell Ms. Harrington this, is unknown. Again, Ms. Harrington will never know what Dr. Argotte's testimony would have been, because she was denied the opportunity to call him to testify. Regardless of whether lack of informed consent could be obvious and apparent to a layperson, it is possible that all issues relating to "standard of care" may have been undisputed. An expert witness would never be required, or even helpful, when the standard of care is undisputed.

It would have been up to the jury to weigh the credibility of both Ms. Harrington and Dr. Argotte, and decide whom to believe. An expert witness would not have aided the jury in determining which witness was telling the truth. The trial court took away Ms. Harrington's chance to demonstrate by the evidence that an expert witness would be of no assistance to the jury.

It was reversible error for the trial court to rule as a matter of law that an expert was required without hearing the evidence and at least considering the possibility that the evidence would demonstrate that expert testimony would not be required. The decision made by the trial court could not have properly been made until after Ms. Harrington had completed her proof. If this Court finds that there was even a slight possibility that the evidence could have shown that an expert witness was not needed, even on one facet of Ms. Harrington's claim, it must affirm the decision of the Kentucky Court of Appeals.

G. CONCLUSION

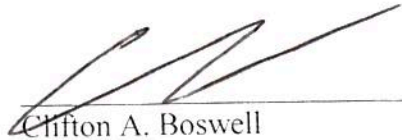
Under Kentucky law, a party appealing entry of directed verdict normally can point to the evidence that was presented, and make a case to the appellate court that the directed verdict should be reversed. Ms. Harrington, however, is in the unenviable

position of arguing what the proof at trial *would have been*. The fact that Ms. Harrington is being forced to anticipate--and in some cases, speculate-- before this Court what the evidence *might have been* rather than *what it was*, demonstrates the injustice of the ruling of the McCracken Circuit Court.

There can be no question that the McCracken Circuit Court was treading on very shaky ground by entering a directed verdict prior to any evidence being introduced, no matter what the circumstances were. In this case, Ms. Harrington's evidence could very well have shown that an expert witness was not required. The trial court should have permitted Ms. Harrington to present her evidence, and only thereafter, entertained a motion for directed verdict, viewing all the evidence in a light most favorable to her.

By rendering a directed verdict prior to presentation of evidence--what normally occurs only with a summary judgment--the McCracken Circuit Court seeks to blur the line between a motion for directed verdict and a motion for summary judgment. Upholding this entry of directed verdict would encourage litigants to present last-minute surprise dispositive motions at trial prior to the introduction of evidence, undermining the notice requirements for a motion for summary judgment under CR 56. This Court should uphold the procedures established under Kentucky law for a trial court presented with a motion for directed verdict, and affirm the unanimous decision of the Kentucky Court of Appeals.

Respectfully submitted this the 24th day of May, 2016



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